EC-2000-007
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To: docket.oeca@epamail.epa.gov
cc:
Subject: Docket Number EC-2000-007 // Electronically submitted comments

The following text comments are hereby submitted electronically. Paper-based copies of these comments with the referenced Accenture report have been mailed and should arrive by November 29.

Greg McCarney
3M Regulatory Affairs

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November 26, 2001

United States Environmental Protection Agency
Enforcement and Compliance Docket and Information Center
Mail Code 2201A
1200 Pennsylvania Avenue NW.
Washington, DC, 20460

Electronic delivery at: docket.oeca@epa.gov

Attn: Docket Number EC-2000-007

Dear Sir or Madam:

The Environmental Protection Agency proposed a rule concerning the reporting and management of digital records on August 31 (66 FR 46161-46195). The proposal covers protocols for transmitting digital data to the Agency, and the verification, storage and archiving of digital data in any form that is used in support of a reporting requirement. The proposed rules for management of digital records would apply whether or not the report is filed on paper or electronically.

3M is hereby taking the opportunity to comment on this proposal, which we believe would impose significant costs on all regulated entities. 3M is a diversified global producer of consumer, commercial, industrial and professional products.

Introduction

3M supports the goal of voluntary electronic reporting options. We believe voluntary electronic submissions of regulatory data and records will over time result in greater efficiency for the government and the regulated community. We believe that the EPA will derive the greatest benefit from a transition to electronic reporting, since it will greatly ease burdens of transcribing paper records to electronically accessible databases. But regardless of who will benefit more from the establishment of electronic reporting provisions, 3M supports a move to put in place reasonable standards and processes for electronic data reporting.

However, 3M opposes the overall proposal at 66 FR 46161-46195 for several

reasons. We believe the proposed reporting and records management rule is in fact not voluntary, despite EPA's claim. 3M also opposes the proposal because in the context of a non-voluntary rule, the electronic records management provisions would be very costly and burdensome to large and small businesses, as well as reporting units of government. The proposal would threaten the universe of existing electronic data management systems that were not designed to comply with EPA's proposed provisions. Further, the proposal seems to defeat the goals of an electronic records initiative, based on EPA's own prediction in the proposed rule, of an extremely low level of participation, due to the burdensome records management requirements.

3M believes that the subject of electronic reporting and records management is a very significant matter, which should be developed through a very detailed and balanced design process. Such a proposed rule should receive a thorough and preferably independent cost-benefit analysis.

Following is a limited discussion of specific citations from the proposed rule and reasons for our positions.

The Proposed Rule Is Not Voluntary
The proposal states:

1) "Under today's proposal, electronic document submission or electronic recordkeeping will be totally voluntary; EPA will not require the submission of electronic documents or maintenance of electronic records in lieu of paper documents or records." (66 FR 46162)

However, our understanding of the proposed rule indicates this is not true, because the rule would enact total regulation of all electronic records. Our review of the total proposal, of a comparison with the effects of a parallel FDA rule (at 21 CFR Part 11), and the results of recent regulatory discussions that included EPA representatives have demonstrated that the proposal is not voluntary. We believe the rule as written would in fact create highly burdensome compliance requirements for those who keep electronic records, even if they submit reports in a paper medium.

In contrast to citation (1) above, the proposed rule also states:

2) "For regulated entities that choose to keep records electronically, today's proposal requires the adoption of best practices for electronic records management." [page 46164]

This proposal does not concern itself only with entities that might voluntarily elect to submit records electronically. It regulates on a non-voluntary basis all regulated entities that keep electronic records. It is likely that almost all regulated entities already keep electronic records to some degree. The records may be kept on a few or many software systems or products. The record keeping software may have been custom designed and implemented, or may be commercially available products, or both. Based on citation number (2), it is clear that EPA's proposed rule would implement detailed, costly compliance requirements for management of electronic records. The 'best practices' that are referenced are described in nine major performance criteria, at 66 FR 46190 and 46191. These records management systems would also be subject to Agency inspection under the terms of the conditions listed in the proposal.

The non-voluntary aspect of the proposal is also illustrated by the citation at page 46190, Section 3.100:

3) (a) An electronic record or electronic document will satisfy a recordkeeping requirement of an EPA-administered federal environmental program under this Title only if it is generated and maintained by an acceptable electronic record-retention system as specified under this subsection. For purposes of maintaining electronic records that satisfy recordkeeping requirements under this Title, an acceptable electronic record-retention system must: [(a)1-9, (b)]

The proposed rule would apply to all regulated entities that keep any kind of electronic record of information that is reported or is used in support of a reporting requirement, even if the final report is submitted by paper. The stipulation at (3) means that all entities who currently keep records electronically, and whose systems and software presumably do not meet EPA's criteria, would not be in compliance. The thousands of large and small businesses and government units that would be subject to the proposal, would be
forced to adopt the records management systems referenced in citation (3) if they keep relevant digital data on a computer system.

The Proposal Imposes Substantial Costs of Compliance
The proposed rule states that it will:

4) "remove existing regulatory obstacles to electronic reporting and record-keeping". [66 FR 46163, B.]

We believe the proposal will in fact create its own major obstacles to electronic record keeping, through the terms and conditions it imposes for management of electronic records.

To keep a compliant record that would qualify as supporting information for a reporting requirement, a regulated entity must adopt stringent and costly records management systems - systems or system-modifications that may not exist today. The required features of those records management systems are so technically detailed and costly that EPA assumed that only 0.5% of facilities would implement them. [page 46178]

We draw inferences on the costs of complying with the proposal from the pharmaceutical industry's experience with a similar rule (21 CFR Part 11). A credible study by Accenture Consulting* estimated that the impact of the FDA version of this rule could be greater in cost to the affected companies than their Y2K remediation costs. The Accenture report also estimated total compliance costs at greater than 100 million dollars for leading pharmaceutical companies, with continuing maintenance costs.

The proposed rule would mandate standards for electronic records that would be clearly expensive to implement, because existing electronic records systems or commercially available software products do not comply and were generally not designed to meet the proposed criteria. Regulated entities currently rely on various software products and systems to manage electronic records that are used to produce or support environmental reports. In a large company, the electronic systems can be numerous, and can include:

- production management records

- order management systems
- emissions monitoring systems
- electronic analytical systems
- waste disposal records databases
- environmental permit databases
- import and Customs records
- regulated chemical lists and threshold data
- TSCA and FIFRA databases of alleged adverse incidents
- export databases, including TSCA Section 12b records
- electronic reporting forms and forms management software
- other environmental and regulatory databases

Some of the electronic information systems listed above can probably not be converted or retrofitted to achieve the EPA's criteria. The systems above may be standalone data resources or interactive with other systems in the data they hold or transmit to support a company's regulatory compliance and reporting activities. As existing legacy electronic systems and products used for supporting or directly reporting regulatory data, they would likely all be non-compliant if the proposed rule were in effect. It should be obvious that implementation of the proposed requirements would represent a huge, costly and
non-voluntary mandate for regulated entities.

We believe the costs indicated in the proposal substantially under-state the true cost of compliance to businesses and government agencies. The apparent non-voluntary nature of the proposal suggests that close to 100% of the many thousands of regulated entities would be subject to the expensive records management requirements of the proposal.

Are the Costs of Compliance Necessary?
We believe the proposed records management requirements over-reach and are not
necessary.

The EPA has prescribed measures in the proposal that are designed to create inviolate, fraud-proof electronic records. In our view, the measures proposed go beyond the needs of environmental reporting. We would like to point out that many paper-based records are today certified as to the accuracy and truthfulness of the data submitted through the signature of an official representative of the submitter. A parallel approach for electronic records would be sufficient.

A digital signature of an electronically transmitted document can explicitly serve as the submitter's legal certification that the data are accurate and truthful at the time of submission. Such an approach would enable the continued use of legacy electronic data systems which are in place today, and were developed expressly to store and provide regulatory data, or databases that are queried to obtain information in support of a regulatory reporting requirement.

The electronic information systems in use today already store and provide data to support reporting or Agency inspection inquiries. The EPA has not cited a problem with their acceptance of or the reliability of records printed from electronic data systems, or a concern that any significant level of fraud occurs with their use. Therefore, we do not see the justification, need, or ability to practically implement the records management criteria at 66 FR 46190-46191.

The justification and need for the Agency's approaches to records management seem absent from the proposal, and the benefits to the EPA do not seem proportional to the likely costs of compliance. We urge the Agency to consider a different strategy than the current proposal, and one that is reasonable for all stakeholders.

Standards for Confidential Business Information (CBI) are Lacking
Although the proposal notes that the current design of a central data exchange (CDX) is not intended to handle confidential data, the scope of the rule would not exclude such highly sensitive data in the future. However, there are no standards presented in the proposed rule for the protection of such data. The EPA states that it does intend to enhance CDX to accommodate CBI (page 46167), but at this time, we cannot assess the adequacy of the technology or procedural protections that could be specified in the future.

We believe CBI data should be excluded from the scope of any rule concerning electronic records until the protections for transmission and storage of such data can be clearly explained by the Agency and evaluated by the regulated community for their potential effectiveness. The scope of this proposal should be limited to non-confidential data.

Conclusion
3M thanks the EPA for its consideration of these comments. We summarize our
comments and concerns with the following points:

a) We believe the proposal should be withdrawn, due to the serious issues stated above.

b) The proposal is not voluntary, as it claims to be, since it imposes Agency control over existing electronic records systems. The proposal would condition the keeping of such records on substantial and costly non-voluntary mandates listed in the proposal, and would render obsolete many current voluntary electronic records systems.

c) The cost to comply with the proposed rule would be very large for many thousands of regulated entities, even if they continued to report via a paper medium, due to the records management requirements. We believe these requirements are over-reaching and unnecessary.

d) The aggregate cost of compliance with the proposal as a non-voluntary rule should be evaluated for its potential "economically significant" impact, and an independent cost-benefit analysis should be conducted. This proposal appears certain to have a major regulatory compliance impact on large and small businesses and units of government. The expectation of very high costs of compliance under the proposal do not seem to be balanced by potential benefits.

e) We recommend that a dialogue take place between the EPA and all stakeholders to help determine which record retention requirements are truly necessary, and to develop the best approach to enabling electronic reporting of data to the Agency.

Sincerely,

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*Accenture Consulting White Paper, "21 CFR Part 11", page 9, www.accenture.com.

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